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Our Docket No. EBL 102
Your Docket No.

Client/Matter No. 084647/00004

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MESSAGE:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Abraham J. Domb and Joseph S. Wolnerman

Serial No.: 10/083,413 Art Unit: 1654

Filed: February 27, 2002 Examiner: Flood, Michele C.

For: *ABSORBABLE SOLID COMPOSITIONS FOR TOPICAL TREATMENT OF ORAL MUCOSAL DISORDERS*

Attachments
Fee Transmittal Form PTO/SB/17
Transmittal Form PTO/SB/21
Appeal Brief

{45058186.1}

PTO/SB/21 (09-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission: 3

Application Number	10/083,413
Filing Date	February 27, 2002
First Named Inventor	Abraham J. Domb et al.
Art Unit	1654
Examiner Name	Michele C. Flood
Attorney Docket Number	EBL 102

ENCLOSURES *(Check all that apply)*

- [✓] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [✓] Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
- [ ] Proprietary Information
- [ ] Status Letter
- [ ] Other Enclosure(s) (please identify below):

Remarks

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Firm Name	Pabst Patent Group LLP		
Signature			
Printed name	Patrea L. Pabst		
Date	June 27, 2005	Reg. No.	31,284

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FEE TRANSMITTAL For FY 2005

☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 250.00

Complete if Known	
Application Number	10/083,413
Filing Date	February 27, 2002
First Named Inventor	Abraham J. Domb et al.
Examiner Name	Michele C. Flood
Art Unit	1654
Attorney Docket No.	EBL 102

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES Fee ($)	FILING FEES Small Entity Fee ($)	SEARCH FEES Fee ($)	SEARCH FEES Small Entity Fee ($)	EXAMINATION FEES Fee ($)	EXAMINATION FEES Small Entity Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee ($)	Fee Paid ($)	Multiple Dependent Claims Fee ($)	Multiple Dependent Claims Fee Paid ($)
27 - 27 or HP =	_____ x	_____ =	_____	_____	_____

HP = highest number of total claims paid for, if greater than 20

Indep. Claims	Extra Claims	Fee ($)	Fee Paid ($)
1 - 3 or HP =	0 x	_____ =	_____

HP = highest number of independent claims paid for, if greater than 3

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee ($)	Fee Paid ($)
_____ - 100 =	_____ / 50 =	_____ (round up to a whole number)	x _____	= _____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other: Appeal Brief	$250.00

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 31,284	Telephone (404) 879-2151
Name (Print/Type)	Patrea L. Pabst		Date June 27, 2005

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant: Abraham J. Domb and Joseph S. Wolnerman

Serial No.: 10/083,413 Art Unit: 1654

Filed: February 27, 2002 Examiner: Flood, Michele C.

For: *ABSORBABLE SOLID COMPOSITIONS FOR TOPICAL TREATMENT OF ORAL MUCOSAL DISORDERS*

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APPEAL BRIEF

Sir:

This is an appeal from the final rejection of claims 1-4, 6-12, 14-26, and 38 in the Office Action mailed January 25, 2005, in the above-identified patent application. A Notice of Appeal was filed on April 25, 2005. The Commissioner is hereby authorized to charge $250.00, the fee for the filing of this Appeal Brief for a small entity, to Deposit Account No. 50-3129.

It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-3129.

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(1) REAL PARTY IN INTEREST

The real party in interest of this application is the assignee Axiomedic, Inc. of Raanana, Israel.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to appellant, the undersigned, or appellant's assignee which directly affects, which would be directly affected by, or which would have a bearing on the Board's decision in this appeal.

(3) STATUS OF CLAIMS

Claims 1-4, 6-12, 14-26, and 38 are pending. Claims 35-37 were canceled in the Second Supplemental Amendment mailed on July 22, 2004. Claims 13 and 27-34 were canceled in the Supplemental Amendment mailed on June 9, 2004. Claim 5 was canceled in the Response Under 37 C.F.R. § 1.114(c) mailed on March 23, 2004. Claims 1-4, 6-12, 14-26, and 38 are on appeal.

(4) STATUS OF AMENDMENTS

An amendment after final rejection was mailed on November 17, 2004 along with a Request for Continued Examination. In the Final Office Action mailed January 25, 2005, the Examiner indicated that the amendment filed on November 17, 2004 would be entered. An appendix sets forth the claims on appeal.

(5) SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 is directed to a solid, self-bioadhesive composition for topical application that adheres to the oral mucosal tissue (page 10, lines 21-23). The composition

comprises a bioactive amount of at least one herbal active agent selected from the group consisting of bioactive herbs, herbal extracts (page 18, line 1 to page 19, line 17), tinctures (page 17, lines 19-31), essential oils (page 11, lines 3-9 and page 17, lines 8-15), and mixtures thereof; *or* an agent selected from the group consisting of analgesics, anti-inflammatories, antihistamines, antigens, steroids other than anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial, antiulcer drugs, peptides, and combinations thereof (page 11, lines 14-18), wherein the agent is present in a homeopathic amount, which is less than a therapeutically effective amount (page 35, Example 8); and a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa (page 10, lines 25-27).

Dependent claims 2-3 define the composition of claim 1 in the form of a disk with a diameter of 2 to 15 mm and a thickness of 0.4 to 2.3 mm (page 27, lines 9-11) that adheres to the oral mucosal tissue for at least 30 minutes, preferably at least one hour to about 24 hours (page 22, lines 14-18).

Dependent claims 4 and 6-8 define the bioactive herbs, herbal extracts, tinctures and essential oils recited in claim 1 (page 10, line 28 to page 11, line 2; page 11, lines 3-9; page 17, lines 4-31; and page 18, line 27 to page.19, line 17).

Dependent claim 9 defines the composition of claim 1 wherein the herbal active agent is at least one monoterpene with three unsaturations (page 19, line 29 to page 20, line 2).

Dependent claim 10 defines the composition of claim 1 wherein the herbal active agent is an essential oil which is a natural or synthetic mixture consisting of limonene and at least one

myrcene, a-pinene, b-pinene, and sabinene characterized in that at least 60% by weight of the mixture is limonene. Dependent claim 11 defines the composition of claim 1 wherein the monoterpene with three unsaturations is a citrus oil selected from the group consisting of lemon oil, pomelo oil, citron oil, and combinations thereof (page 20, lines 3-19). Dependent claim 19 recites the composition of claim 1 wherein the active agent consists of a mixture of natural or synthetic monoterpenes with three unsaturations selected from the group consisting of limonene, myrcene, pinenes, sabinene, and terpinene.

Dependent claim 12 defines the composition of claim 1 further comprising a salt selected from the group consisting of $MgBr_2$, NaCl, and KCl (page 38, Example 9). Dependent claim 14 defines the composition of claim 1 further comprising Carnallite or a salt of Carnallite (page 32, Example 6). Dependent claim 18 recites the composition of claim 14 wherein the Carnallite or salt of Carnallite improves the activity of the herbal active agents (page 32, Example 6).

Dependent claim 15 defines the composition of claim 1 further comprising a non-herbal active agent (page 11, lines 12-18). Dependent claim 16 defines the composition of claim 15 wherein the non-herbal active agent is selected from the group consisting of at least one base or acid-addition salt of procaine, lidocaine, prilocaine, mepivacaine, dyclonine, dibucaine, benzocaine, chloroprocaine, tetracaine, bupivacaine, and etidocaine (Example 9). Dependent claim 17 defines the composition of claim 15 wherein the non-herbal active agent is selected from the group consisting of at least one base or acid-addition salt of dexamethasone, triamcinolone, hydrocortisone, amphotericine, B, nystatin, itraconazole, chlorhexidine, quaternary ammonium salts, parabens, and dextranase enzymes (Example 9).

Claim 20 recites the composition of claim 15 comprising a citron oil and Carnallite salt at a ratio of 1:10 to 1:1 (page 33, Example 6). Claim 21 recites the composition of claim 15 comprising a citron oil and Carnallite salt at a ratio of 1:10 to 1:1 and a local anesthetic selected from the group consisting of lidocaine, benzocaine, and bupivecaine (page 32, Example 6).

Dependent claim 22 defines the composition of claim 1 wherein the bioadhesive carrier is selected from the group consisting of a natural, semisynthetic or synthetic polyhydric polymer, a polycarboxylic acid polymer and mixtures there of (page 12, lines 8-21). Dependent claim 23 defines the composition of claim 22 wherein the polyhydric polymer is selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxyethylcellulose, carboxymethyl cellulose, dextran, arabinogalactan, pullulan, guar-gum, hyaluronic acid, pectins, starch derivatives, acrylic acid polymers, polymer of acrylic acid esters, acrylic acid copolymers, polymers of vinyl alcohols, alkoxy polymers, polyethylene oxide polymers, polyethers and combinations thereof (page 13, lines 10-17). Claim 26 defines the composition of claim 22 wherein the solid bioadhesive carrier is selected from polyacrylic acid polymers lightly crosslinked with a polymer selected from the group consisting of polyalkenyl polyether, carboxymethylceullose, hydroxymethylcellulose, and mixtures thereof (page 13, lines 3-9).

Claim 24 defines the composition of claim 1 further comprising an excipient selected from the group consisting of fillers, tableting excipients, lubricants, enhancers, flavors, taste-masking agents, pH controlling compounds, dyes, stabilizers, enzyme inhibitors, and mixtures thereof (page 21, line 11 to page 22, line 13). Claim 25 defines the composition of claim 24 wherein the enhancers are selected from the group consisting of bile acids and limonene.

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues presented on appeal are:

(1) whether claims 1-4, 6-12, 14-26 and 38 satisfy the written description requirement as required by 35 U.S.C. § 112, first paragraph.

(2) whether claims 1-4, 6-12, 14-26 and 38 are definite as required by 35 U.S.C. § 112, second paragraph.

(3) whether claims 1, 4, 6-8, 22 and 24 are novel as required by 35 U.S.C. § 102(b) over Green, The Herbal Medicine-Maker's Handbook, A Home Manual, 276-285, The Crossing Press, (2000) ("Green").

(4) whether claims 1, 4, 7, 15-17, 22-24, are novel as required by 35 U.S.C. § 102(e) over U.S. Patent No. 6,159,498 to Tapolsky *et al.* ("Tapolsky").

(5) whether claims 1-4, 15-17, 22-24, 26, and 38 are non-obvious as required by 35 U.S.C. § 103(a) over Tapolsky.

(6) whether claims 1-4, 6-8, 22, 24, and 38 are non-obvious as required by 35 U.S.C. § 103(a) over Green in view of Tapolsky.

(7) whether claims 1-4, 6-11, 15-17, 19, 22-24, 26, and 38 are non-obvious as required by 35 U.S.C. § 103(a) over Tapolsky in view of U.S. Patent No. 5,939,050 to Iyer *et al.* ("Iyer") and U.S. Patent No. 6,197,305 to Friedman *et al.* ("Friedman") with evidence provided by Lawless, The Illustrated Encyclopedia of Essential Oils, Element Books, 1995 ("Lawless")

(8) whether claims 1-4, 6-12, 15-17, 19, 22-24, 26, and 38 are non-obvious as required by 35 U.S.C. § 103(a) over Tapolsky in view of Friedman and U.S. Patent No. 6,207,137 to Shuch *et al.* ("Shuch").

(7) GROUPING OF CLAIMS

The claims do not stand or fall together, as discussed in more detail below.

(8) ARGUMENTS

(a) The Claimed Invention

The claims are directed to a solid, self-bioadhesive composition for topical application to oral mucosal tissue to which it adheres. The composition comprises a bioactive amount of at least one herbal active agent: a bioactive herb, herbal extract, tincture, essential oil, or mixture thereof; or an analgesic, anti-inflammatory, antihistamine, antigen, steroid other than an anti-inflammatory, antimicrobial drug, vitamin, enzyme, antipyretic, antimalarial, antiulcer drug, peptide, or combination thereof, *wherein the agent is present in a homeopathic amount*. This is discussed in more detail below but is typically defined as an amount which is less than the amount which is normally considered to be required for efficacy. The composition further comprises a pharmaceutically acceptable solid bioadhesive carrier present in an amount from about 40 to about 99 percent by weight of the whole composition. Claims 4, 6, 7, 8, 9, 10, 11, 19, 20, and 25 are specific to herbal formulations.

The compositions can be prepared by forming a solid powder of an herbal active agent by drying the herbal liquid extract with an inert compound. The dried herbal extract powder is mixed with the bioadhesive component and one or more lubricants and the mixture is

compressed into tablets of the desired size and shape. These compositions, and in particular those formed into the disks of claims 2 and 3, are prepared by *compression molding* rather than solvent casting. Solvent casting typically requires drying at elevated temperatures in order to remove the solvent. Herbal extracts and essential oils can be extremely sensitive to heat and can degrade at elevated temperatures thereby destroying their therapeutic effectiveness.

The bioadhesive carrier is a material that attaches to mucosal tissue upon hydration. The carrier must be capable of maintaining adhesion in moist or wet environments *in vivo*. The final composition is self-adhesive in that it attaches to the site of interest without the need to reinforce its attachment by way of another adhesive which is applied to a backing. The composition should adhere to mucosal tissue for at least 30 minutes, preferably from about 1 to about 24 hours, more preferably from about 3 to about 10 hours, as defined by claims 2 and 3. Suitable bioadhesive carriers include polysaccharides such as cellulose derivatives such as cellulose acetate, carboxymethylcellulose, and hydroxymethyl cellulose and partially esterified polyacrylic acid polymer such as polyacrylic acid polymers crosslinked with polyalkenyl polyethers, as defined by claims 22, 23, and 26. The compositions can further comprise excipients such as humectants, flavoring agents, sweetening agents, coolants, salivating agents, and numbing agents, as defined by claim 24.

(b) Rejections under 35 U.S.C. § 112, first paragraph

The Legal Standard

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the

inventor had possession of the claimed invention. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed, *In re Wertheim*, 541 F.2d at 262, 191 USPQ at 96.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of Univ. of Cal. v. Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991). "Compliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" *Enzo Biochem, Inc. v. Gen-Probe*, Inc., 296 F.3d at 1324, 63 USPQ2d at 1613.

The Claimed Invention

The claims define solid, self-bioadhesive compositions for topical application that adhere to oral mucosal tissue. The compositions comprise

a bioactive amount of at least one bioactive herb, herbal extract, tincture, essential oil, mixture thereof or an analgesic, anti-inflammatory, antihistamine, antigen, steroid other than anti-inflammatory, antimicrobial drug, vitamin, enzyme, antipyretic, antimalarial, antiulcer drugs, peptides, and combinations thereof,

wherein the agent is present in a homeopathic amount, which is less than a therapeutically effective amount; and

a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa.

Claims 1-4, 6-12, 14-26 and 38 comply with the written description requirement

The examiner has rejected claim 38 as lacking written description for the phrase "wherein the agent is present in a homeopathic amount, which is less than a therapeutically effective amount".

The examiner has not provide an explanation of why claims 1-4, 6-12, and 14-26 lack written description.

The specification *defines* homeopathy as a therapeutic approach based on the concept that disease conditions should be cured by administering drugs which, in healthy people, induce a symptom similar to that manifested by the disease one intends to treat (page 35, lines 16-19). Also typical of homeopathic treatments is that extremely low, sometimes infinitesimal (spelling in original application was incorrect), doses of the homeopathic remedy must be given in order to induce the desired therapeutic effect, whereas high doses of the same drug would actually cause

the symptom picture of the disease one is seeking to cure (page 35, lines 19-23). Further support is found at pages 35-36. The specification therefore clearly defines a homeopathic amount of an agent which is less than the amount normally required to produce a desired pharmacological effect. Therefore, the claims satisfy the written description requirement.

(c) Rejections under 35 U.S.C. § 112, second paragraph

The Legal Standard

Definiteness of claim language must be analyzed, not in a vacuum, but in light of the content of the particular application disclosure, the teachings of the prior art, and the claim interpretation that would be given by one possessing the ordinary skill in the pertinent art at the time the invention was made. The test for definiteness under 35 U.S.C. 112, second paragraph, is whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. (*Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986)).

Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if appellants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph.

During patent examination, the pending claims must be given the broadest reasonable interpretation consistent with the specification. *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969). See also

MPEP § 2111 - § 2111.01. When the specification states the meaning that a term in the claim is intended to have, the claim is examined using that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art. *In re Zietz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989).

Claims 1-4, 7-12, 14-26, and 38 are definite

The examiner rejected claim 1 on the basis that the phrase "which is less than a therapeutically effective amount" is unclear. Claim 6 was rejected for lack of antecedent basis for "wherein the herbal active agent or homeopathic agent".

Claim 1 recites a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising a bioactive amount of at least one herbal active agent selected from the group consisting of bioactive herbs, herbal extracts, tinctures, essential oils, and mixtures thereof or an agent selected from the group consisting of analgesics, anti-inflammatories, antihistamines, antigens, steroids other than anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial, antiulcer drugs, peptides, and combinations thereof, wherein the agent is present in a homeopathic amount, which is less than a therapeutically effective amount; and a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa.

The term "homeopathic agent" is discussed above, with respect to the disclosure at pages 35-36, and would be clearly understood by those skilled in the art based on this disclosure.

The phrase is also generally known to those skilled in the art. In the Amendment and Response, filed on November 17, 2005, the appellants submitted the definition of homeopathy from Stedman's Medical Dictionary (Exhibit A) as well as information from the National Institutes of Health website (Exhibit B). Copies of these submissions are enclosed. Stedman's Medical Dictionary defines a homeopathic agent as an extremely small does of a pharmacological agent wherein the dose is too small to produce the effect usually expected from the agent. The information from the National Institutes of Health website makes it clear that homeopathic agents are well known and accepted and have been regulated by the FDA since 1938 in the same way as other over the counter medications.

Claim 6 is definite

Claim 1 recites a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising a bioactive amount of *at least one herbal active agent* or *an agent* selected from the group consisting of analgesics, anti-inflammatories, antihistamines, antigens, steroids other than anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial, antiulcer drugs, peptides, and combinations thereof, *wherein the agent is present in a homeopathic amount.*

An agent present in a homeopathic amount is a homeopathic agent. There is sufficient antecedent basis in claim 1 for the recitation "homeopathic agent" in claim 6.

The subject matter of claims 1-4, 6-12, 14-26, and 38 is defined with a reasonable degree of particularity and distinctness.

(d) Rejections Under 35 U.S.C. § 102

The Legal Standard

For a rejection of claims to be properly founded under 35 U.S.C. § 102, it must be established that a prior art reference discloses each and every element of the claims. *Hybritech Inc. v Monoclonal Antibodies Inc.*, 231 USPQ 81 (Fed. Cir. 1986), cert. denied, 480 US 947 (1987); *Scripps Clinic & Research Found v. Genentech Inc.*, 18 USPQ2d 1001 (Fed. Cir. 1991). The Federal Circuit held in Scripps, 18 USPQ2d at 1010:

> Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . *There must be no difference* between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. (Emphasis added)

A reference that fails to disclose even one limitation will not be found to anticipate, even if the missing limitation could be discoverable through further experimentation. As the Federal Circuit held in Scripps, Id.:

> [A] finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill in the gaps in the reference.

For a prior art reference to anticipate a claim, it must enable a person skilled in the art to practice the invention. The Federal Circuit held that "a §102(b) reference must sufficiently describe the claimed invention to have placed the public in possession of it. . . [E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling." Paperless Accounting Inc v Bay Area Rapid Transit Sys., 231 USPQ 649, 653 (Fed. Cir. 1986).

Claims 1, 4, 6-8, 22 and 24 Are Novel Over The Herbal Medicine-Maker's Handbook, A Home Manual by James Green, Chapter 24, (2000) ("Green").

Claims 1, 4, 6-8, and 24 are Novel

Green fails to disclose at least two elements of the claims: bioadhesive and agent present in a homeopathic amount.

Green describes the preparation of poultices, which are defined as local baths that utilize warmth and moisture to relax tissue and relieve pain (page 277, second column, 1st paragraph). Herbal preparations can be incorporated to enhance the therapeutic properties of poultices (page 277, second column, 1st paragraph). Green describes the procedure for making a bentonite clay poultice for the mouth, teeth and gums for reducing the inflammation of an abscessed tooth (page 285). Step 5 instructs the reader to *hold the poultice in place*. Indeed, at page 278, col. 2, the reader is instructed on how to prevent the poultice from sticking! Therefore, Green does not disclose a *self-bioadhesive composition* as claimed by the appellants.

Green also does not disclose compositions comprising an agent . . ., *wherein the agent is present in a homeopathic amount*. The only reference to the amount of herbal agent is found at

page 277, col. 2, which provides for "Medicated, which are intended to exercise a specific influence on a part of the body,". There is no reference to low amounts, or homeopathic amounts. Accordingly, the claims are novel over Green.

Claim 22 is Novel

Claim 22 recites the composition of claim 1 wherein the solid bioadhesive carrier is selected from the group consisting of natural, semisynthetic or synthetic polyhydric polymer, a polycarboxylic acid polymer and mixtures thereof. Green discloses the preparation of a bentonite clay poultice for the mouth, teeth and gums (page 285). Bentonite is a clay mineral, the main component of which is the mineral Montmorillonite. Montmorillonite is a hydrous aluminum silicate. Bentonite is composed of layers of aluminum silicate sandwiched between layers of silicon dioxide.

Bentonite is not a natural, semi-synthetic or synthetic polyhydric polymer, polycarboxylic acid polymer or mixture thereof. Accordingly, claim 22 is novel over Green.

Claims 1, 4, 7, 15-17, 22-24, and 26 Are Novel Over U.S. Patent No. 6,159,498 to Tapolsky *et al.* ("Tapolsky")

Tapolsky does not anticipate the claims because, at a minimum, Tapolsky does not disclose incorporation of herbal agents or other agents in a homeopathic amount nor a solid bioadhesive carrier in an amount from about 40 to 90 percent by weight.

Tapolsky describes a water-soluble, bioerodible pharmaceutical delivery device for application to mucosal surfaces, the device comprising a bilayer film disk having an adhesive layer and a non-adhesive backing layer wherein the pharmaceutically active agent is in one or

both layers (col. 4, lines 2-5). The adhesive layer may comprise one film-forming water-soluble polymer and at least one pharmaceutically acceptable polymer known for it bioadhesive properties (col. 5, lines 40-44). The non-adhesive backing layer may comprise a water-soluble film-forming pharmaceutically acceptable polymer (col. 6, lines 38-40). The pharmaceutical component can comprise a single pharmaceutical or a combination of pharmaceuticals. Suitable pharmaceutical agents are disclosed at col. 7, line 13 to col. 8, line 12).

Tapolsky does not disclose or suggest the use of bioactive herbs, herbal extracts, tinctures or essential oils, as required at a minimum by claims 4, 6, 7-11, 19-21. Tapolsky discloses thymol and eugenol as examples of pharmaceuticals that can be incorporated into the bilayer composition. Thymol and eugenol are single compounds which are isolated from natural sources. Herbs, herbal extracts, tinctures and essential oils are mixtures of compounds, not a single compound, nor are they either of thymol or eugenol. Further, the compositions described in Tapolsky are prepared by solvent casting and the resulting films are dried at temperatures between 90 and 130°C. Herbal compositions and essential oils are highly sensitive to heat and easily evaporate when exposed to temperatures as low as 50°C, even for short periods of time. It is clear that Tapolsky does not disclose or even suggest the incorporation of herbal extracts, tinctures or essential oils. There is no mention of incorporating a sub-therapeutic or homeopathic amount.

Tapolsky also does not disclose a pharmaceutically acceptable bioadhesive carrier in an amount from *about 40 to 99 percent by weight of the whole composition.* Tapolsky states that the ratio of bioadhesive polymer to the film forming polymer may vary depending on the type of

pharmaceutical and the amount of pharmaceutical to be used (col. 6, lines 27-30). However, the content of combined components in the adhesive layer is between 5 and 95% by weight, preferably between 10 and 80% by weight (col. 6, lines 30-32). Tapolsky does not disclose if the content of the combined components of the adhesive layer is by weight of the adhesive layer ***or*** by weight of the whole composition, i.e. adhesive layer plus non-adhesive backing layer. Example 17 describes the preparation of a bioadhesive, bilayer film. The adhesive layer contains 74.6% by weight water, 1.8% by weight hydroxyethyl cellulose, 2.6% by weight polyacrylic acid, 4.5% by weight sodium carboxymethylcellulose, 2.5% by weight benzocaine and 14.0% by weight ethanol. The non-adhesive backing layer contains 87.98% by weight water, 0.02% by weight FD&C red dye, and 12% by weight hydroxyethyl cellulose. Assuming all the solvent is removed during drying, which is unlikely, the mass of the film is 23.42 grams (sum of the masses of the adhesive layer and the backing layer after drying if one assumes a 100 gram sample). The bioadhesive materials in the adhesive layer are polyacrylic acid (2.6% by weight or 2.6 grams assuming a 100 gram sample) and sodium carboxymethyl cellulose (4.5% by weight or 4.5 grams assuming a 100 gram sample). The percent of the bioadhesive materials by weight of the total composition in Example 17 is 7.1 grams/23.42 grams or 30.32%. The percent by weight of the bioadhesive materials drops to 24.98% by weight of the whole composition if one assumes that 5% water remains after drying. Example 18 describes the preparation of a bilayer film wherein the bioadhesive layer is not fully dried. Therefore, Tapolsky does not disclose, expressly or inherently, a composition wherein the pharmaceutically acceptable

bioadhesive carrier is present in an amount from about 40% to about 99% by weight of the whole composition. Therefore, the claims are novel over Tapolsky.

(e) Rejections Under 35 U.S.C. § 103

The Legal Standard

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

"There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however without a motivation to combine, a rejection based on a prima facie case of obvious was held improper.). The level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999). "In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be

sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

Claims 1-4, 15-17, 22-24, 26, and 38 Are Non-Obvious over Tapolsky

As discussed above, Tapolsky does not disclose incorporating a homeopathic amount of a herbal agent or one of the named drugs, nor a bioadhesive carrier in an amount of 40 to 99 percent based on weight.

There is no teaching at all to modify the amount of carrier or active agent, much less a teaching of how or why or what result should be obtained.

There is no disclosure of the specific sizes of claims 2, 3 and 38, nor anything leading one to these compositions.

One of ordinary skill in the art would not be motivated to modify the teachings of Tapolsky to prepare the claimed compositions. Accordingly, the claims are not obvious over Tapolsky.

Claims 1-4, 6-8, 22, 24, and 38 Are Non-Obvious over Green in view Tapolsky

As discussed above, Green does not disclose a *self-bioadhesive composition* as claimed by the appellants. Rather, Green teaches compositions which must be held in place in order to be effective. Tapolsky also fails to disclose a solid, self-bioadhesive composition, *wherein the agent is present in a homeopathic amount*, which is less than a therapeutically effective amount; and a *pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99*

percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa. Neither discloses a homeopathic amount.

Green therefore does not make up for the deficiencies in Tapolsky. One of ordinary skill in the art would not be motivated to combine the teachings of Green and Tapolsky to prepare the claimed compositions, nor if one combined Green and Tapolsky would one arrive at the claimed compositions. Accordingly, the claims are not obvious over Green in view of Tapolsky.

Claims 1-4, 6-11, 15-17, 22-24, 26, and 38 Are Non-Obvious Over Tapolsky In View of Iyer and Friedman with Evidence from Lawless

Tapolsky is discussed above.

U.S. Patent No. 5,939,050 to Iyer *et al.* ("Iyer") describes antimicrobial compositions comprising at least two antimicrobial agents which exhibit reduced MIC values relative to the MIC values for the agents making up the combination when measured alone (abstract). Suitable plant extracts and essential oils which can be used as antimicrobial agents are described at col. 5, line 49 to col. 6, line 27). Iyer does not disclose a solid, self-bioadhesive composition for topical application that adheres to the oral mucosal tissue. Iyer does not disclose a homeopathic amount; Iyer discloses the use of combinations to provide an effective amount, where either component alone is ineffective. Iyer therefore does not provide the elements missing from Tapolsky, at a minimum, a homeopathic amount and between 40 and 99% by weight bioadhesive carrier.

U.S. Patent No. 6,197,305 to Friedman *et al.* ("Friedman") discloses an anti-fungal composition containing (a) an extract of botanical materials; and (b) an essential oil, in a ddefined amount that is therapeutically effective (col. 2, lines 20-59; col. 4, lines 5-9; see also

examples at col 6-10). Friedman discloses that the compositions are suitable for local oral, mucosal, topical, intra-nasal, and intra-vaginal administration. Friedman does not disclose a solid, self-bioadhesive composition for topical application that adheres to the oral mucosal tissue. The formulations are not bioadhesive. Ingredients such as those at col. 7 are either hydrophobic (such as beeswax) or liquid (glycerin and oil) or contain detergent (such as sodium lauryl sulfate). Table 3 is liquid, not solid. Table 4 is a gel primarily of polyethylene glycol, which is not bioadhesive alone. Table 7 is similar. Tables 5 and 6 are hydrophobic skin cream. Example 10 contains similar examples to the other examples.

Accordingly, Friedman does not provide the elements missing from Tapolsky and Iyer.

Lawless discloses that the essential oil of lemon contains approximately 70% limonene as well as sabinene, myrcene, and pinenes (page 120). Lawless does not disclose a self-bioadhesive composition for topical application that adheres to oral mucosal tissue, nor a homeopathic amount.

No where is there any disclosure of the size ranges defined by claims 2, 3 and 38.

In summary, the prior art fails to disclose each claimed element and the motivation to modify what is disclosed and combine it as appellants have done. It is well established that it is not sufficient to merely identify art and then assert that it would be obvious to combine: the motivation must come from the references. Such hindsight is impermissible. The prior art must lead one skilled in the art to what is claimed. The art cited by the examiner does not do this.

Claims 1-4, 6-11, 15-17, 22-24, 26, and 38 Are Not Obvious Over Tapolsky In View of Friedman and Shuch

Tapolsky is discussed above.

Friedman discloses an anti-fungal composition containing (a) an extract of botanical materials; and (b) an essential oil. Friedman does not disclose or even suggest a solid self-bioadhesive composition for topical application that adheres to oral mucosal tissue.

Shuch discloses an orally absorbable dental formulation which includes a base to which one or more active components, such as vitamin C and co-enzyme Q-10, can be added (abstract). The composition can be a toothpaste, mouthwash, or chewing gum (col. 2, lines 5-9) and can be used in conjunction with dental treatments such as prophylaxis paste and irrigation fluids (col. 2, lines 9-13). Formulations such as toothpastes, mouthwashes and chewing gums have short contact times, typically on the order of a few seconds. As described in the specification, the claimed bioadhesive formulations adhere to the oral mucosal tissue for at least 30 minutes, preferably from about 1 hour to 24 hours, more preferably from about 3 hours to about 10 hours.

Shuch does not disclose or even suggest a solid self-bioadhesive composition for topical application that adheres to oral mucosal tissue, nor a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa.

Shuch does not disclose a homeopathic amount.

None of the art discloses the size comositions of claims 2, 3, and 38.

None of the cited art discloses the combinations of claims 14-18.

Nowhere does the prior art provide the motivation to combine these elements as appellants have done. It is well established that it is not sufficient to merely identify art and then assert that it would be obvious to combine: the motivation must come from the references.

(9) SUMMARY AND CONCLUSION

The rejection under 35 U.S.C. § 112, first paragraph for lack of written description is improper. The appellants have clearly described homeopathy and homeopathic agent so that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

The rejection under 35 U.S.C. § 112, second paragraph is improper. The subject matter of claims 1-4, 6-12, 14-26, and 38 is defined with a reasonable degree of particularity and distinctness, and one skilled in the art would have no trouble determining the scope of the claimed subject matter.

With respect to the rejections under 35 U.S.C. § 102, both Green and Tapolsky fail to disclose a solid self-bioadhesive composition for topical administration to the oral mucosal surface comprising a bioactive amount of at least one herbal active agent selected from the group consisting of bioactive herbs, herbal extracts, tinctures, essential oils, and mixtures thereof or an agent selected from the group consisting of analgesics, anti-inflammatories, antihistamines, antigens, steroids other than anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial, antiulcer drugs, peptides, and combinations thereof, wherein the agent is present in a homeopathic amount, which is less than a therapeutically effective amount; and a

pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa.

With respect to the rejections under 35 U.S.C. § 103, the prior art fails to disclose, at a minimum,

A homeopathic amount of agent;

A solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa;

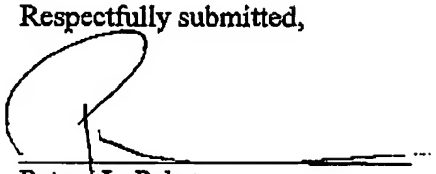
The size ranges of the claimed compositions

The combination of carnalite or salt of carnallite.

The prior art also fails to provide the motivation to combine or modify as appellants have done. It is well established that it is not sufficient to merely identify art and then assert that it would be obvious to combine: the motivation must come from the references.

For the foregoing reasons, Appellant submits that claims 1-4, 6-12, 14-26, and 38 are patentable.

Respectfully submitted,



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